

Docket. 59597-D/JPW/JML/CMR

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Neil T. Parkin and Rainer A. Ziermann

Serial No. : 09/766,344

Filed : January 19, 2001

For : MEANS AND METHODS FOR MONITORING PROTEASE

INHIBITOR ANTIRETROVIRAL THERAPY AND GUIDING THERAPEUTIC DECISIONS IN THE

TREATMENT OF HIV/AIDS

1185 Avenue of the Americas

New York, New York 10036

May 18, 2001

Honorable Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

## TRANSMITTAL OF VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS UNDER 37 C.F.R. §1.9(f) AND §1.27(d)

Applicants submit as **Exhibit 1** a Verified Statement (Declaration) Claiming Small Entity Status under 37 C.F.R. \$1.9(f) and \$1.27(d) signed by Mr. William D. Young. The Verified Statement is signed by an authorized official of the entity who has rights in the subject application, namely, ViroLogic, Inc.

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No fee is deemed necessary in connection with the filing of this However, if any fee is required, authorization Communication. is hereby given to charge the amount of any such fee to Deposit Account 03-3125.

Respectfully submitted,

hereby certify that correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

John P. White

No. 28,678

Date

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John R. White

Registration No. 28,678 Attorney-for Applicants Cooper & Dunham LLP 1185 Avenue of the Americas New York, New York 10036

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EXHIBIT 1

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or Patentee: Neil T.	Parkin and Rainer A. Ziermann Attorney's JPW/CMR
Serial or Patent No.: 09/766,	344 Docket No.: 59597-D
anuary	· 19. 2001
minle of Invention or Patent:	MEANS AND METHODS FOR MONITORING PROTEASE INHIBITO
Title of invention	ANTIRETROVIRAL THERAPY AND GUIDING THERAPEUTIC
	DECISIONS IN THE TREATMENT OF HIV/AIDS
verified :	STATEMENT (DECLARATION) CLAIMING
SMALL ENTI	TY STATUS UNDER 37 C.F.R. \$1.9(f)
AND \$1.	27(d) - SMALL BUSINESS CONCERN
I hereby declare that I am:	
I nereby deciate that I amo	
the owner of the sma	ll business concern identified below.
· ·	
an official of the sm	all business concern empowered to act on behalf of the
concern identified be	elow:
Concern recorded	
Name of Concern:	ViroLogic, Inc.
Name of Concern-	
Address of Concern:	270 East Grand Avenue
Address of company	South San Francisco, CA 94080
the above	e identified small business concern qualifies as a
concerns are affiliates of eac	to control the other, or a third party or parties
concern controls or has power	1 back
controls or has power to contro	
	der contract or law have been conveyed to and remain
I hereby declare that rights und	n identified above with regard to the invention
with the small business concer	n identified above with regard to
entitled	THERAPY AND
MEANS AND METHODS FOR MONITORI	NG PROTEASE INHIBITOR ANTIRETROVIRAL THERAPY AND
GUIDING THERAPEUTIC DECISIONS	IN THE TREATMENT OF HIV/AIDS
described in:	
•	
the specification filed	herewith
Timetion corial no of	0/766 2% Illed January 17,2001
patent no.	issued
If the rights held by the above i	dentified small business concern are not exclusive,
any concern which could not	t organization under 37 C.F.R. \$1.9(e)*.
C.F.R. §1.9(d) or as a nonprofit	t organization in inches
37 / 4	
Name: N/A	
Address:	
	Nonprofit Organization
Individual Small	Business Concern Nonprofit Organization

anore: Separate verified statements are required for each named person, concern, or

- (c) An independent inventor as used in this chapter means any inventor who (1) has not assigned, granted, conveyed, or licensed, and (2) is under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not likewise be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section.
- (d) A small business concern as used in this chapter means any business concern as defined by the Small Business Administration in 13 C.F.R. §121.3-18, published on September 30, 1982 at 47 FR 43273. For the convenience of the users of these regulations, that definition states:
- \$121.3-18 Definition of small business for paying reduced patent fees under Title 35, U.S. Code.
- (a) Pursuant to Pub. L. 97-247, a small business concern for purposes of paying reduced fees under 35 U.S. Code 41(a) and (b) to the Patent and Trademark Office means any business concern (1) whose number of employees, including those of its affiliates, does not exceed 500 persons and (2) which has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit For the purpose of this section concerns are organization under this section. affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both. The number of employees of the business concern is the average over the fiscal year of the the persons employed during each of the pay periods of the Employees are those persons employed on a full-time, part-time or temporary basis during the previous fiscal year of the concern.
- (b) If the Patent and Trademark Office determines that a concern is not eligible as a small business concern within this section, the concern shall have a right to appeal that determination to the Small Business Administration. The Patent and Trademark Office shall transmit its written decision and the pertinent size determination file to the SBA in the event of such adverse determination and size appeal. Such appeals by concerns should be submitted to the SBA at 1441 L Street, NW., Washington, D.C. 20416 (Attention: SBA Office of General Counsel). The appeal should state the basis upon which it is claimed that the Patent and Trademark Office initial size determination on the concern was in error; and the facts and arguments supporting the concern's claimed status as a small business concern under this section.
- (e) A nonprofit organization as used in this chapter means (1) a university or other institution of higher education located in any country; (2) an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)(3)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)); (3) any nonprofit scientific or educational organization qualified under a nonprofit organization statute of a state of this country (35 U.S.C. 201(i)); or (4) any nonprofit organization located in a foreign country which would qualify as a nonprofit organization under paragraphs (e)(2) or (3) of this section if it were located in this country.

Small Entity/Small Business Concern Page -2-

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. 37 C.F.R. §1.28(b)\*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. \$1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Mr. William D. Young		
Chairman and CEO		
ViroLogic, Inc., 270	East Grand Avenue	
South San Francisco,	CA 94080	
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5/9/01		
	Chairman and CEO ViroLogic, Inc., 270 South San Francisco,	Chairman and CEO ViroLogic, Inc., 270 East Grand Avenue South San Francisco, CA 94080

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(b) Once status as a small entity has been established in an application or patent, fees as a small entity may thereafter be paid in that application or patent without regard to a change in status until the issue fee is due or any maintenance fee is due. Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application or patent prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate pursuant to \$1.9 of this part. The notification of change in status may be signed by the applicant, any person authorized to sign on behalf of the assignee, or an attorney or agent of record or acting in a representative capacity pursuant to \$1.34(a) of this part.